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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/758,036	01/11/2001	Ekkehard Leberer	38005-0126	8288

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BELL, BOYD, & LLOYD LLC  
P. O. BOX 1135  
CHICAGO, IL 60690-1135

EXAMINER

JOIKE, MICHELE K

ART UNIT PAPER NUMBER

1636

DATE MAILED: 04/13/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

Application No.

09/758,036

Applicant(s)

LEBERER ET AL.

Examiner

Michele K. Joike, Ph.D.

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 08 February 2006.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-10,20-23 and 25 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-10,20-23 and 25 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some \* c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_\_
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_

### **DETAILED ACTION**

A request for continued examination under 37 CFR 1.114 was filed in this application after appeal to the Board of Patent Appeals and Interferences, but prior to a decision on the appeal. Since this application is eligible for continued examination under 37 CFR 1.114 and the fee set forth in 37 CFR 1.17(e) has been timely paid, the appeal has been withdrawn pursuant to 37 CFR 1.114 and prosecution in this application has been reopened pursuant to 37 CFR 1.114. Applicants' submission filed on February 8, 2006 has been entered.

Claims 1-10, 20, 21 and 25 are pending and under consideration in the instant application. Any rejection of record in the previous Office Action, mailed January 6, 2005, that is not addressed in this action has been withdrawn.

### ***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-3, 20 and 21 rejected under 35 U.S.C. 103(a) as being unpatentable over Gaber in view of Ketchum et al and Fairman et al as recited in the previous Office Actions. This rejection is maintained for the reasons set forth in the previous Office Action.

Claims 1-10, 20, 21 and 25 are rejected under 35 U.S.C. 103(a) as being unpatentable over Gaber in view of Ketchum et al and Fairman et al as applied to claims 1-3, 20 and 21 above, and further in view of Tang et al and Rampe et al, as set forth in the previous Office Actions. This rejection is maintained for the reasons set forth in the previous Office Action.

***Response to Arguments Concerning Claim Rejections - 35 USC § 103***

Applicants' arguments filed January 05, 2006 have been fully considered but they are not persuasive. Applicants provide the following grounds of traversal:

1. Gaber teaches a single mutant that is equivalent to the double mutant so there is no suggestion or motivation for making a third mutant.
2. Fairman et al teach that TRK1 and TRK2 are dominant channels and TOK1 is a passive channel with unknown function under normal conditions, therefore TRK1 and TRK2 overshadow TOK1, so there is no motivation to use a TOK mutant.
3. Tang et al do not teach a triple mutant.
4. The mutants of Fariman et al are too fragile, which would teach away from mutating it further.
5. There is no reasonable expectation of success for obtaining expression of a potassium channel in a triple mutant; there is no reasonable expectation of success that complementation would occur; and certain human channels do not complement the double mutant.

6. Tang et al and Rampe et al do not cure the deficiencies of Gaber, Fariman et al and Ketchum et al.

Applicants' arguments have been considered, but are not found convincing for the following reasons:

1. Gaber does not teach a triple mutant, however, Fairman et al teach the triple mutant,  $\Delta trk1$ ,  $\Delta trk2$  and  $\Delta tok1$ , which is the triple mutant claimed.
2. Fairman et al teach a triple mutant,  $\Delta trk1$   $\Delta trk2$  and  $\Delta tok1$ , therefore they made and used a TOK1 mutant. Fariman et al also teach a strain  $\Delta J0911$  which contains  $tok1::URA3$ . Ketchum et al teach that TOK1 is a potassium channel.
3. Fariman et al teach the triple mutant.
4. There is no evidence that the  $\Delta trk1$ ,  $\Delta trk2$  and  $\Delta tok1$  mutant is too fragile in Fariman et. al; there is no teaching away from mutating it further. Fariman et al report that the triple mutant grows less well than the  $trk1\Delta$   $trk2\Delta$  double mutant, but that is to be expected of a strain that has an additional mutation.
5. The combination of references for the instant rejection is the same as the situation in Takekawa et al (which was successfully implemented), where a triple deletion is provided to accurately allow for the complementation of a phenotype by a heterologous gene. In the instant case, Gaber teaches an assay involving the deletion of TRK1 and TRK2 from a cell, where a heterologous potassium ion channel is expressed to overcome the phenotype of TRK1 and TRK2. However, Ketchum et al and Fairman et al teach that there is a third gene that can endogenously complement the deletion of

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TRK1 and TRK2. Given the pattern seen in the prior art as exemplified by Takekawa et al, wherein a triple deletion of three genes with a common function was used to accurately represent the complementation of a phenotype, the ordinary skilled artisan would have had a reasonable expectation of success when combining the references of Gaber, Ketchum et al and Fairman et al to construct a *trk1Δ trk2Δ tok1Δ* strain to allow accurate complementation of the strain by a heterologous potassium ion channel.

Although according to applicant, certain human channels do not complement double mutants, it is clear that not all heterologous potassium ion channels have such trouble complementing the double deletion phenotype. This is evident from Tang et al, which indicates that the *gplRK1* gene complements the double deletion strain (*trk1Δ trk2Δ*). Therefore, one of ordinary skill in the art would have a reasonable expectation of success expressing *gplRK1* in the triple deletion.

6. First, applicants did not argue any deficiencies in Ketchum et al. Second, as discussed above, there are no deficiencies in Fairman et al and Gaber to be overcome.

### ***Allowable Subject Matter***

No claims are allowed.


Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michele K. Joike, Ph.D. whose telephone number is 571-272-5915. The examiner can normally be reached on M-F, 9:00-6:30.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Irem Yucel, Ph.D. can be reached on 571-272-0781. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Michele K Joiike, Ph.D.  
Examiner  
Art Unit 1636

  
DAVID GUZO  
PRIMARY EXAMINER